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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,851	03/23/2005	Philip C. Roy	2870(203-3505)	6326
Paul R Audet	7590 02/28/200	EXAMINER		
Tyco Healthcare Group United States Surgical Senior Patent &Trademark Counsel 150 Glover Avenue Norwalk, CT 06856			TRUONG, THANH K	
			ART UNIT	PAPER NUMBER
			3721	
SHORTENED STATUTO	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MC	ONTHS	02/28/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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	Application No.	Applicant(s)			
	10/528,851	ROY, PHILIP C.			
Office Action Summary	Examiner	Art Unit			
	Thanh K. Truong	3721			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period value of the reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>30 N</u>	ovember 2006.				
2a)⊠ This action is <b>FINAL</b> . 2b)□ This	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims					
4)⊠ Claim(s) <u>1-9 and 19</u> is/are pending in the application.					
4a) Of the above claim(s) <u>10-18</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) <u>1-9 and 19</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	r election requirement.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10)⊠ The drawing(s) filed on <u>23 March 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.					
Applicant may not request that any objection to the	***				
Replacement drawing sheet(s) including the correct					
11) The oath or declaration is objected to by the Ex	raminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).			
a)⊠ All b)□ Some * c)□ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the prior	•	ed in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
	or the certified copies flot receive	····			
Attachment(s)	A) Thing ian Com-	/DTO 412)			
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)   Interview Summary Paper No(s)/Mail Da	ate			
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 11-30-06.  5) Notice of Informal Patent Application  Other:					
1 apei 110(5)/111aii Dale 11-30-00.	3) <u></u> .				

Art Unit: 3721

#### **DETAILED ACTION**

1. This action is in response to applicant's amendment received on November 30, 2006.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Viola et al. (5,954,259).

Viola et al. discloses an apparatus comprising:

<u>a housing</u> having a fixed handle (20) - It is construed that <u>the housing</u> in Viola et al. comprises the frame portions that cover all components of the apparatus (10) – see figure 1;

a clamping handle (44) mounted to the housing and selectively movable relative to the fixed handle from a first position in spaced relation relative to the fixed handle to a second position closer to the fixed handle to actuate the clamping of tissue;

an adapter yoke (76) which translates within the housing upon actuation of the clamping handle, the adapter yoke mechanically cooperating with a lead screw (78) disposed within the housing to actuate the tool assembly to clamp tissue;

a drive assembly (22) disposed within the housing, the drive assembly including a shaft (42), the shaft being mechanically engaged with the lead screw (78) disposed

Art Unit: 3721

within the housing such that upon selective activation of the drive assembly, the shaft rotates said lead screw to advance a roll nut (94) distally along the lead screw to force a firing piston into a tool assembly when mounted on the housing to deform the surgical fasteners through and fastening the tissue (figures 9 & 10).

Regarding claims 8 and 9, wherein the stapler includes a switch for reversing the rotation of the shaft of the drive assembly upon activation thereof (column 5, lines 7-12), and the shaft (42) rotates upon activation of the drive assembly (22), which in turn rotates the lead screw (78).

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Green et al. (US 2002/0096550).

As discussed above in paragraph 3 of this office action, Viola et al. discloses the claimed invention, but does not expressly disclose that: the drive assembly is pneumatic powered, the safety mechanism as describe in claims 5 and 7.

It is old and well known in the art to employ a pneumatic drive assembly in place of electrical or hydraulic drive assembly and it is also well known to have a safety mechanism in a surgical stapler to prevent accidental triggering of the device.

Art Unit: 3721

Green et al. discloses a surgical stapler that comprising: a pneumatic drive assembly (68) to provide a simple and compact drive system, and a safety mechanism to prevent from accidentally firing of the tool (page 6, [0102]).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al. apparatus by incorporating the pneumatic drive assembly for a more compact and simple drive system and the safety mechanism as taught by Green et al..

6. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Mizzy et al. (3,859,996).

As discussed above in paragraph 3 of this office action, Viola et al. discloses the claimed invention, but does not expressly disclose that the drive assembly is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger.

Mizzy et al. discloses an apparatus that comprises a pressure sensitive trigger mechanism (abstract) that provides a means to effectively controlling the drive assembly.

Mizzy et al. demonstrates that it is old and well known in the art to use the pressure sensitive trigger to activate and regulate the drive assembly of an apparatus so that drive assembly is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger (as recited in claims 3 and 4) to provide a more accurately control of the stapler device.

Art Unit: 3721

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al. apparatus by incorporating the pressure sensitive trigger mechanism as taught by Mizzy et al. so that it comprises the drive assembly that is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger mechanism to provide a more responsive and more precise surgical instrument.

### Response to Arguments

- 7. Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive.
- 8. In response to the Applicant's argument that "Viola does not teach or suggest that these elements [adapter yoke (76), a lead screw (78) and a roll nit (94)] operatively translate within the housing", this is not found persuasive, because as mentioned above in paragraph 3 of this office action, and the examiner maintains that **the housing** in Viola et al. comprises the frame portions that cover all components of the apparatus (10), in other words, the housing includes all cover portions for holding or protecting the mechanical parts of the apparatus (10) see figure 1.
- 9. In response to the Applicant's argument that:
  - "Viola does not disclose that drive assembly is pneumatic powered. However, the Office Action attempts to cure the above deficiency by asserting that employing a pneumatic drive assembly in place of electrical or hydraulic drive assembly is old and well known. Applicant's respectfully invite the Examiner to introduce relevant art in Applicant's field of

Art Unit: 3721

endeavor, <u>i.e., surgical staplers</u>, in support of this assertion" (emphasis added),

this is not found persuasive, because the following reasons:

Firstly, Green et al. (US 2002/0096550) is relied upon to demonstrate that it is old and well known in the art to employ a pneumatic drive assembly in place of electrical or hydraulic drive assembly.

Secondly, the apparatus in Green et al. (US 2002/0096550) is a <u>surgical</u> stapler (please see the reference).

10. Applicant's arguments with respect to claims 3 and 4 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Application/Control Number: 10/528,851 Page 7

Art Unit: 3721

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Thanh K. Truong whose telephone number is 571-272-

4472. The examiner can normally be reached on Mon-Thru 8:00AM - 6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hanh K. Truong

Patent Examiner

February 23, 2007.